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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/806,253

03/22/2004

David C. Baulcombe

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EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

02/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/806,253 | <b>Applicant(s)</b><br>BAULCOMBE ET AL. |  |
|                              | <b>Examiner</b><br>JENNIFER PITRAK   | <b>Art Unit</b><br>1635                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-37,39-41,47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 33,34,39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32,35,36,41,47 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/491549.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

### ***Remarks***

Applicants' responses filed 10/31/07 have been considered. Applicants amended claim 32.

Rejections and/or objections not reiterated from the previous office action mailed 08/06/07 are hereby withdrawn. The rejections and/or objections set forth in this Office Action are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Restriction and Election of Species**

This application contains claims 33, 34, 39, and 40 that are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Restriction was required

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among the species, A) plant, B) mammal, C) insect, D) avian, E) reptile, F) protozoan, and G) nematode in the restriction requirement mailed 05/23/2006. Applicants elected “mammal” with traverse in their response dated 06/26/2006. Accordingly, claims 33, 34, 39, and 40 are withdrawn as directed to non-elected species. Claims 33 and 34 are to plant and nematode, respectively. Claims 39 and 40 are to plant-specific phenomena as clearly defined in the specification, pathogen-derived resistance and co-suppression (see instant specification p.5, lines 12-26; p.23, lines 15-24).

Claims 32, 35-37, 41, 47, and 49 are under examination.

#### Priority

Applicants' arguments filed 10/31/07 regarding the priority claim have been considered and are persuasive. Thus, Applicants' claim for the benefit of a prior-filed application under 119(e) or under 35 U.S.C. 120, 121 or 365(c) applies to all pending claims except for claim 41. Thus, claims 32, 35-37, 47, and 49 are granted the priority date of 10/27/1999 and claim 41 is granted the filing date of parent application, 09/491549, filed 01/26/2000.

#### Art Rejections

Applicant's amendments and/or arguments filed 10/31/07, with respect to the rejection(s) of claim(s) under 35 USC 102(b) over **(A)** Agrawal, *et al.* (WO 94/01550) as further evidenced by Bridge, *et al.* (2003, Nature Genetics, v.34:263-264, 2<sup>nd</sup> paragraph) and **(B)** Baracchini, *et al.* (US 5,801,154) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Rejection under 35 U.S.C. § 112, first paragraph (new matter)

Applicants' amendment to claim 32 has obviated this rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 35, 36, 37, 41, 47, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Crooke (2000, U.S. Patent 6,107,094, filed 06/06/1997) as evidenced by Claycomb and Lanson (1987, Biochem. J., v.247:701-6).

The claims are to a method of detecting PTGS of a target gene in an organism wherein the method comprises 1) analyzing a nucleic acid extract from the organism to determine the presence or absence of short RNA molecules (SRMs) of 20-30 nucleotides in length and 2) characterizing any SRMs which are present to determine sequence identity or similarity with the target gene, wherein the presence of any SRMs having sequence identity or similarity with the target gene indicates silencing of the target gene in the organism. The claims are further to the described method wherein the organism is mammal, the SRMs are either sense or antisense, or wherein the target gene is involved in apoptosis, cell-cycle regulation, or a neurological process.

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Claim 41 specifies that the characterization step of the method is performed by preparing a library of genes from the organism and identifying those genes with sequence identity or similarity. The claims and specification broadly disclose PTGS, analyzing, and characterizing. Thus, the claims are interpreted in their broadest reasonable scope.

Crooke teaches 20-base-pair RNA duplexes (sense and antisense strands), which were analyzed and characterized in that the precise sequence of each strand was known and they were known to have identity to the rat *C-raf* gene (i.e. characterized; see columns 50-51, Table I). *C-raf* is a proto-oncogene (Claycomb and Lanson, abstract). These RNA molecules were added to rat liver cytosolic and nuclear extracts, which nuclear extract contains a library of rat genes in which resides a RNA duplex specific double stranded RNase. The substrates for this assay were later detected and thus analyzed (see column 50 and 51). Furthermore, Crooke teaches at column 14, lines 14-16, that the oligoribonucleotides of the present invention comprise from about 15 to about 25 nucleoside subunits. Thus, Crooke anticipates the instant claims 32, 35, 36, 37, 41, 47, and 49.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak  
Examiner  
Art Unit 1635

/J. D. Schultz, Ph.D./  
Supervisory Patent Examiner, Art Unit 1635